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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,797	11/26/2003	Javier Alarcon	P-6013	4139

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DAVID W. HIGHET
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC110
FRANKLIN LAKES, NJ 07417

EXAMINER	
BERHANU, ETSUB D	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,797	ALARCON ET AL.	
	Examiner	Art Unit	
	Etsub D. Berhanu	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/26/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17, 19-42* is/are rejected.

7)☒ Claim(s) *18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/26/2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Element 10, Figure 2. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because Figure 8 does not depict 'an embodiment of the present invention including multiple electromagnetic energy detectors and an internal reference' as stated in the brief description of the drawings. In addition, the Reporter Group and Reference Group are non-

distinguishable on the graph provided in Figure 8. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The abstract of the disclosure is objected to because:

a. it contains legal phraseology ("disclosed" in line 2; "comprises" in lines 4 and 6) and,

b. the sentence "An optical conduit, preferably an optical fiber has an optical system at the proximal end of the optical conduit" (lines 2-3) is unclear. Correction is required. See MPEP § 608.01(b).

6. The use of the trademarks Loctite 4011, Pronova, and TexasRed, have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

7. Claim 18 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 4, 10, 11, 14, 15, 34 and 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the inner surface" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "the inner surface" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the inner surface" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the inner surface" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "the inner surface" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 34 and 36-39 are unclear when the reference group is not included in the device [as permitted by use of the term "optionally" in the independent claim], since these claims require that the reference group be present to define the limitations that they set forth.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 5-9, 12-13, 16-17, 19-27, 20-30, 33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Alcala'405 (US Patent No. 5,127,405).

Regarding claims 1-3, Alcala'405 discloses a fiber optic device for monitoring chemical and/or physical conditions within the bodies of living subjects comprising an optical conduit (Figure 1, fiber 43) having a proximal end (Figure 1, proximal end 44) and a distal end (Figure 1, distal end 45); an optical system (col. 5, lines 27-44) at the proximal end of the optical conduit comprising an electromagnetic

energy emitter (Figure 1, light source 30) and an electromagnetic energy detector (Figure 1, detector 56); a sensing element in optical proximity to the distal end of the optical conduit comprising at least one biding protein (Figure 2, element 48) adapted to bind with at least one target analyte and at least one reporter group (Figure 2, element 49) associated with the binding protein, wherein the reporter group is adapted to undergo a luminescence change upon binding of the binding protein to the target analyte (col. 6, lines 8-11, 20-23) and the sensing element is contained within a tip (Figure 2, element 50).

Regarding claim 5, Alcala'405 discloses a fiber optic device wherein the sensing element is directly attached to the distal end of the optical conduit (col. 6, lines 8-11).

Regarding claim 6, Alcala'405 discloses a fiber optic device comprising a connector (col. 6, lines 8-13).

Regarding claim 7, Alcala'405 discloses a fiber optic device wherein the sensing element is attached to the distal end of the optical conduit through a connector (col. 6, lines 8-13).

Regarding claims 8 and 12, Alcala'405 discloses a fiber optic device wherein the sensing element is attached to a polymer chain or matrix (col. 6, lines 8-11).

Regarding claims 9 and 13, Alcala'405 discloses a fiber optic device wherein the polymer chain or matrix is directly attached to the distal end of the optical conduit (Figure 2, matrix 50 attached to distal end 45).

Regarding claims 16 and 17, Alcala'405 discloses a fiber optic device wherein the optical system is attached to the proximal end of the optical conduit through a connector (col. 6, lines 50-53) and the sensing element is attached to the distal end of the optical conduit through a connector (col. 6, lines 8-13).

Regarding claim 19, Alcala'405 discloses a fiber optic device wherein the optical conduit comprises at least one optical fiber (col. 5, lines 61-63).

Regarding claim 20, Alcala'405 discloses a fiber optic device wherein the electromagnetic energy emitter may be a light emitting diode (col. 5, lines 45-53).

Regarding claim 21, Alcala'405 discloses a fiber optic device wherein the electromagnetic energy detector may be a photomultiplier tube (col. 6, lines 60-64).

Regarding claims 22, 23 and 27, Alcala'405 discloses a fiber optic device wherein the optical elements are able to distinguish multiple wavelengths, are comprised of electrical elements for modulation of the luminescence signal received by the detector, and are comprised of optical filters (col. 6, lines 55-68 and col. 7, lines 1- 40, and Figure 2, optical filters 34 and 53).

Regarding claims 24 and 25, Alcala'405 discloses a fiber optic device wherein the electromagnetic energy detector is adapted to detect energy emitted by the reporter group substantially continuously or periodically (col. 17, lines 46-54).

Regarding claims 26, Alcala'405 discloses a fiber optic device wherein the optical system comprises electrical elements for modulation of the signal from the electromagnetic energy emitter (col.5, lines 45-60).

Regarding claims 29 and 30, Alcala'405 discloses a fiber optic device wherein the optical system is adapted to measure the intensity, wavelength and lifetime of the luminescence signal (col. 13, lines 25-37).

Regarding claim 33, Alcala'405 discloses a fiber optic device wherein the tip of the fiber optic device may be framed by metal (col. 6, lines 34-37).

Regarding claim 35, Alcala'405 discloses a fiber optic device wherein the sensing element is further adapted to be inserted through the skin of a patient (col. 7, lines 45-52).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 28, 31, 32 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcala'405 in view of Lakowitz'534 (US Patent No. 6,197,534).

Alcala'405 teaches all the elements of the current invention, as discussed in paragraph 12, except for an optical system adapted to measure the intensity and polarization of the luminescence signal and the energy transfer efficiency of the reporter group, wherein the reporter group comprises a pair of organic dyes chosen so that the energy transfer efficiency between the pair changes upon analyte binding, wherein the reporter group comprises a pair of fusion proteins chosen so that the energy transfer efficiency between the pair changes upon analyte binding and wherein the reporter group comprises an organic dye and a fusion protein chosen so that the energy transfer efficiency between the organic dye and the fusion protein changes upon analyte binding.

In the same field of endeavor, Lakowitz'534 teaches that glucose binding could be detected by changes in emission intensity, polarization, lifetime or energy transfer efficiencies (col. 4, lines 64-67, col. 5, lines 1-3, and col. 6, lines 28-30).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical system of Alcala'405 to measure luminescence intensity, polarization, and the energy

transfer efficiency of the reporter group, as taught by Lakowitz'534, since such spectral changes can be used to detect glucose binding.

Lakowitz'534 also teaches that the reporter group may be comprised of a pair of organic dyes which display resonance transfer energy upon glucose binding (col. 5, lines 16-25).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sensing system of Alcala'405 by using a pair of organic dyes, as taught by Lakowitz'534, since glucose concentration can be measured due to a change in the fluorescent intensity of the reporter group upon glucose binding.

Lakowitz'534 also teaches that the reporter group may be comprised of a pair of fusion proteins which, upon binding with glucose, show a change in their energy transfer efficiency (col. 5, lines 54-57).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sensing system of Alcala'405 by using a pair of fusion proteins, as taught by Lakowitz'534, since glucose concentration can be measured due to a change in the energy transfer efficiency of the reporter group upon glucose binding.

Lakowitz'534 also teaches that a biosensor may include both an organic dye and a fusion protein that exhibit an energy transfer efficiency upon glucose binding (col. 9, lines 44-61).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sensing system of Alcala'405 by using an organic dye and a fusion protein, as taught by Lakowitz'534, since glucose concentration can be measured due to a change in the energy transfer efficiency of the reporter group upon glucose binding.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chick 5342789 teaches a method for measuring glucose concentration using fluorescence resonance energy transfer.

Hellinga 6277627 teaches a genetically engineered biosensor.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571-272-6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on 571-272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDB

ERIC F. WINAKUR
PRIMARY EXAMINER